Brian W. Carroll, Esq.
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Tel.: (973) 639-2020

James P. Rouhandeh, Esq. (*pro hac vice*)
David B. Toscano, Esq. (*pro hac vice*)
DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, NY 10017
Tel.: (212) 450-4000

Neal A. Potischman, Esq. (*pro hac vice*)
Andrew Yaphe, Esq. (*pro hac vice*)
DAVIS POLK & WARDWELL LLP
1600 El Camino Real
Menlo Park, CA 94025
Tel.: (650) 752-2000

Attorneys for Defendant Novo Nordisk Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION	Case No. 2:23-md-3080 (BRM)(RLS) MDL No. 3080
This Document Relates to: *The State of Mississippi, ex rel. Lynn Fitch, Attorney General v. Eli Lilly and Company, et al.* Case No. 2:23-cv-04364 (BRM)(RLS)	

MEMORANDUM OF LAW IN SUPPORT OF MANUFACTURER DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS

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INTRODUCTION

Mississippi's complaint alleges that Eli Lilly and Company, Novo Nordisk Inc., and Sanofi-Aventis U.S. LLC (collectively, "Manufacturers") conspired with pharmaceutical benefit managers ("PBMs") to artificially inflate the list price of insulin, in what it describes as an "Insulin Pricing Scheme" (TAC ¶ 12). The complaint's claims rest on the length of time analog insulin has been on the market, its purported production cost, and its allegedly minimal research and development costs—because, the complaint alleges, the "basic research" on insulin "was performed one hundred (100) years ago." Because of these factors, the complaint alleges that the list prices of certain insulins are inflated and deceptive under state law.

In four paragraphs that are little more than an afterthought, Mississippi (the "State") also tries to sweep multiple novel *non*-insulin medications—glucagon-like peptide-1 receptor agonists ("GLP-1s")—into its so-called "*Insulin* Pricing Scheme." But all of the GLP-1s are on-patent. As such, the State's challenge to the prices of GLP-1s is preempted by federal patent law, which encourages upfront investment in new medications by providing a 20-year period during which pharmaceutical companies and other innovators can recoup their investments through the prices they charge on the patented medications. By creating the patent system, Congress has preempted state laws that seek to regulate patented drug

pricing. State law cannot override that Congressional judgment. Accordingly, the State's claims—which seek to regulate the prices of GLP-1s—are preempted.

The State also does not, and cannot, allege wrongdoing with respect to GLP-1s. None of the allegations upon which the State relies to argue that insulin is priced unlawfully apply to GLP-1s, which are a newer class of drugs that required Manufacturers to invest substantially in research and development costs. Nor does the Third Amended Complaint ("TAC") make any effort to plead any unlawful conduct as to GLP-1s. Indeed, the State's 118-page complaint is silent about GLP-1s, other than a smattering of paragraphs that merely note what the medications are and a figure showing their prices. Because the complaint is devoid of any factual allegations suggesting wrongdoing involving GLP-1s, it fails to state a claim regarding them.

The State's claims as to GLP-1s are both preempted and also inadequately pled, which are independent grounds warranting judgment on the pleadings in favor of Manufacturers and dismissal of the State's claims as to those products.[1]

[1] The State's claims regarding both insulin and GLP-1s are also non-cognizable, including for the reasons set forth in Manufacturer Defendants' Supplemental Brief in Support of Motions to Dismiss in the State Attorney General Track (addressed to the *Illinois* and *Montana* complaints). Following the Court's decision on the *Illinois* and *Montana* complaints, Manufacturers reserve the right to seek judgment on the pleadings as to the *Mississippi* complaint in its entirety.

BACKGROUND

I. Factual Background

Manufacturers are pharmaceutical companies that research, develop, manufacture, and sell medications, including insulin, other diabetes treatments, and non-diabetes treatments. TAC ¶¶ 5, 44, 59, 73, 250. Their non-insulin medications include glucagon-like peptide-1 receptor agonists or GLP-1s.[2] *Id.* ¶¶ 274–77 & Tbl. 1 at 50. GLP-1s are novel, innovative medications that have been engineered to mimic a naturally produced hormone and can be used to treat Type 2 diabetes, among other conditions. *Id.* ¶¶ 274–76.

The Mississippi Attorney General filed this suit on behalf of the State and Mississippi residents with diabetes under the *parens patriae* doctrine. The complaint alleges that Manufacturers and PBMs purportedly engaged in a long-running "Insulin Pricing Scheme"—a phrase that appears no fewer than 184 times in the complaint—that increased the prices the State and its citizens paid for insulin. *E.g.*, *id.* ¶¶ 278–80 (alleging that in "2003, PBMs began their rise to power" and in the "same year, the price of insulin began its dramatic rise to its current exorbitant level"); *see also id.* ¶¶ 349–65, 476–97. The State asserts three state-law claims

[2] The complaint identifies the following four combination or non-insulin medications as being at-issue in the lawsuit: Victoza, Trulicity, Ozempic, and Soliqua. TAC ¶¶ 276–77 & Tbl. 1 at 50. Victoza, Trulicity, and Ozempic are GLP-1s. *Id.* ¶ 276. Soliqua is a combination of GLP-1 and analog insulin. *Id.* This brief uses the term "GLP-1s" to refer to all four of these medications.

against Manufacturers for violation of the Mississippi Consumer Protection Act ("MCPA"), unjust enrichment, and civil conspiracy. *Id.* ¶¶ 521, 529, 537.

The core of the State's factual allegations to support the purported "Insulin Pricing Scheme" are that: (1) insulin is a 100-year-old drug that has not "significantly improved over the last twenty (20) years" (*id.* ¶¶ 248, 250, 261, 264–66); (2) Manufacturers' "production" and "research and development" ("R&D") expenditures have not "increased" but rather "have decreased" for insulin in recent years (*id.* ¶ 267); and (3) despite the foregoing, the price of insulin has "dramatically increased" since 2003 (*id.* ¶¶ 278–86, 289–94). Indeed, part of the impetus for this suit was a report issued by the Senate Financing Committee about insulin pricing—entitled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug"—which the complaint cites extensively. The Mississippi lawsuit also followed—and copied from—a consumer action and other suits bringing similar claims in this Court, all related to insulin pricing.[3]

The complaint points to several studies and public documents that purport to estimate the production cost of insulin and claims that "all of the insulins at issue in this case have either been available in the same form since the late 1990s/early 2000s or are biologically equivalent to insulins that were available then." *Id.* ¶¶ 263–69.

[3] No such claims were asserted as to GLP-1s in the consumer case. *See, e.g.*, *In re Insulin Pricing Litig.*, 2024 WL 416500, at *4 (D.N.J. Feb. 5, 2024) (emphasizing that the pricing scheme alleged in that case involved "analog insulin products").

The complaint also quotes representatives from Manufacturers and PBMs who testified before Congress in 2019 regarding "the rising cost of insulin." *Id.* ¶¶ 366–76. These allegations discuss the history, R&D costs, and production costs of *insulin*.

There are no allegations linking GLP-1s—a new category of drugs engineered after heavy investment in R&D and significant demand for non-diabetes use[4]—to the purported "*Insulin* Pricing Scheme" to inflate the price of a supposedly century-old drug. Rather, the complaint devotes a mere four paragraphs and one figure to GLP-1s. *Id.* ¶¶ 274–276, 295. The entirety of the facts pled as to GLP-1s are: (1) the timeframe—between 2010 and 2017—in which the medications were released (*id.* ¶ 275); (2) the alleged global revenues pertaining to the medications in 2018 and 2019 (*id.* ¶¶ 45–46, 60–61, 74–75); (3) a chart showing the list prices of the medications (*id.* ¶ 295); and (4) a three-sentence description of how they work

[4] *See, e.g.*, TAC ¶ 270 (acknowledging that "research and development costs often make up a large percentage of the price of a drug"); *see also* STAFF OF S. COMM. ON FINANCE, 117TH CONG., INSULIN: EXAMINING THE FACTORS DRIVING RISING COSTS OF A CENTURY OLD DRUG 21 (Comm. Print 2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%C20Report%20(FINAL%201).pdf (hereafter, the "Senate Insulin Report") (noting that as of 2016, Eli Lily "planned to devote a majority of its R&D spending on clinical trials for existing Type 2 diabetes drugs" such as Trulicity); *id.* at 23 (noting that Sanofi spent over $181 million on R&D for Soliqua between 2015 and 2018). The Senate Insulin Report is incorporated by reference in the complaint (TAC ¶ 384) and thus may be considered by the Court. *See Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (courts may consider "any matters incorporated by reference").

medically (*id.* ¶ 276).

Nor do the allegations regarding insulin apply to GLP-1s. In contrast to insulin, GLP-1s are not "century old drug[s]" (*id.* ¶ 384). Rather, as the complaint alleges, the first of them only entered the market in 2010. *Id.* ¶¶ 44, 274–76. These medications were covered by patents at the time the State filed the lawsuit and remain under patent,[5] and Manufacturers spent significant amounts in R&D costs bringing them to market (*see supra* note 4). Moreover, unlike insulin, GLP-1s have been approved, marketed, and have significant benefits for *non-diabetes* uses, such as supporting weight loss and treating cardiovascular events. *E.g.*, Senate Insulin Report at 21 & n.72 (noting that the "FDA approved Trulicity for the reduction of major adverse cardiovascular events in adults with type 2 diabetes"); *see also In re Ozempic (Semaglutide) Patent Litig.*, 621 F. Supp. 3d 1354, 1354–55 (J.P.M.L. 2022) (noting that physicians can prescribe semaglutide "for long-term weight management").

[5] All four GLP-1 medications the State places at issue (TAC ¶ 277 & Tbl. 1) are covered by at least one patent: (1) Victoza: *see, e.g.*, U.S. Patent No. 8,114,833; (2) Trulicity: *see, e.g.*, U.S. Patent Nos.7,452,966; 9,938,335; 10,709,766; 11,541,123; 11,834,486; (3) Ozempic: *see, e.g.*, U.S. Patent Nos. 8,114,833; 8,129,343; 8,536,122; and (4) Soliqua: *see, e.g.*, U.S. Patent Nos. RE45,313; 9,526,764; 9,707,176. *See Choon's Design, LLC v. WeCool Toys Inc.*, 2023 WL 6366325 at n.2 (D.N.J. Sept. 29, 2023) (noting that courts "have taken judicial notice of patent documents for purpose of a motion to dismiss because they are public documents").

II. Procedural History

In October 2021, counsel who now represent plaintiffs in the State Attorney General Track of this MDL filed a complaint in a Mississippi court on behalf of the State. Compl., *Mississippi v. Eli Lilly & Co. et al.*, No. 21-cv-00674 (S.D. Miss. Oct. 21, 2021) ("*Mississippi* Dkt."), Dkt. 1-5. During the Mississippi litigation, Manufacturers moved to dismiss the complaint under Rule 12(b)(6) for failure to state a claim. That motion advanced different arguments than this motion, including that Mississippi failed to allege any misrepresentation as to any product because it conceded that Manufacturers accurately report the list prices of their medications. *Mississippi* Dkt. 84 at 14. The *Mississippi* court rejected that argument in just two sentences, calling Manufacturers' prices "exaggerated" without explanation, and denied the motion. *Mississippi* Dkt. 111 at 13.

The same counsel subsequently filed a motion to form this MDL. After this MDL was formed, counsel for the State Attorney General Track argued (at the initial case management conference) that they were entitled to a larger share of recovery in these cases on the ground that their complaints also include *non-insulin* treatments (i.e., the GLP-1s). 9/12/23 Case Management Conference, Tr. 22:24–10, 44:1–12. In ongoing meet-and-confers, counsel for the State Attorney General Track has asserted that they will insist on fulsome discovery as to these medications.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "after the pleadings are closed—but early enough not to delay trial." Fed. R. Civ. P. 12(c). A party may also move for *partial* judgment on the pleadings. *Haney-Filippone v. Agora Cyber Charter School*, 538 F. Supp. 3d 490, 493 (E.D. Pa. 2021).

A Rule 12(c) motion is governed by the same standards as a Rule 12(b)(6) motion. *Bibbs v. Trans Union LLC*, 43 F.4th 331, 339 (3d Cir. 2022). Thus, to survive such a motion, a complaint must plead "sufficient factual matter to show that the claim is facially plausible, thus enabling the court to draw the reasonable inference that the defendant is liable for [the] misconduct alleged." *Id.*; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face'" (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007))).

ARGUMENT

The Court should grant partial judgment for Manufacturers as to GLP-1 products for two independent reasons. First, all of the State's claims as to GLP-1s are preempted by federal patent law. Second, the State fails to plead any unlawful conduct related to GLP-1s.

I. Claims as to GLP-1s Are Preempted by Federal Law

The State's claims as to GLP-1s are preempted by federal patent law under

binding Federal Circuit precedent. The prices that Manufacturers are able to charge for GLP-1s are governed by patent law, which gives Manufacturers a legal exclusivity for a limited time in exchange for discovering and disclosing these innovative new medications. Under Federal Circuit precedent, which is binding on this Court as to issues of patent law, when state law "stands as an obstacle to the accomplishment and execution of" federal law, the state law "must yield to congressional enactments." *Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1372 (Fed. Cir. 2007).[6]

For patented products, Congress—not the states—is "the promulgator of patent policy." *Id.* at 1372–73. As the Federal Circuit has repeatedly explained, "the Patent Act creates an incentive for innovation. The economic rewards during the period of exclusivity are the carrot . . . . Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace." *Id.* (quoting *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995)); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (same); *Ultra-Precision Mfg. v. Ford Motor Co.*, 411 F.3d 1369, 1378 (Fed. Cir. 2005) (same); *see also Schor v. Abbott Labs.*, 457 F.3d 608, 610 (7th Cir. 2006) ("a patent

[6] "Federal Circuit law governs whether federal patent protections preempt a state law claim." *Southeastern Pa. Transp. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 702 (E.D. Pa. 2015) (citing *Ultra Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1376 (Fed. Cir. 2005)).

holder is entitled to charge whatever the traffic will bear"). Congress balances the "disparate goals" of rewarding innovation and "keep[ing] prices reasonable," *Biotechnology*, 496 F.3d at 1373, by granting innovators of new medications patents with exclusive rights for a limited period—after which others can enter the market. State law claims that seek to "penaliz[e] high prices—and thus limit[] the full exercise of the exclusionary power that derives from a patent" are an improper attempt to "re-balance the statutory framework of rewards and incentives" that Congress created. *Id.* at 1373-74. Thus, such claims are preempted.

Another court in this Circuit applied this Federal Circuit precedent to squarely reject an attempt to use state law to allege—like Mississippi does here—that the price of on-patent prescription drugs was "excessive, . . . exorbitant and inflated." *Southeastern Pa. Transp. Auth. v. Gilead Sciences, Inc.*, 102 F. Supp. 3d 688, 696 (E.D. Pa. 2015). The court held that state law claims were preempted because "plaintiffs simply cannot invoke state law to challenge [the defendant's] overall pricing scheme for its patented drugs." *Id.* at 707; *see also id.* at 707-08 (explaining that "federal patent law preempts the use of state law to reassess or challenge the balance Congress has struck between patent rights and public access"). As the court explained, "Federal patent law contemplates the tradeoffs between exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing [the manufacturer] to lower its prices or disgorge profits from the sale of its patented

drugs." *Id.* at 703.

Mississippi makes the same claims here, alleging that Defendants' "scheme" has rendered the price of diabetes medications, including GLP-1s, "excessive," "exorbitant," and "grossly inflated and false." TAC ¶¶ 30, 279, 359, 361, 522. As the State alleges, the premise of the "Insulin Pricing Scheme" is that "Manufacturer Defendants artificially and willingly raise their prices," which has led to "outrageously inflated price[s]" from which "Defendants . . . profit immensely." *Id.* ¶¶ 17–18, 20. According to the State, "the price increases of [insulin] are untethered from market fundamentals, *i.e.*, unrelated to legitimate cost increases or changes in supply and demand." *Mississippi* Dkt. 98, Pl.'s Mem. in Opp'n to Defs.' 12(b)(6) Mot. to Dismiss, at 13. Its suit seeks to create a new system that would lead to lower prices that the complaint describes as prescribing a "legal, competitive, and fair market value." TAC ¶ 522.

This attempt is squarely preempted as to patented drugs because it seeks to change the way Manufacturers price their patented medications. As *Gilead* held, "plaintiffs cannot use state law to . . . forc[e] [a drug manufacturer] to lower its prices." 102 F. Supp. 3d at 703; *see also Biotechnology Indus.*, 496 F.3d at 1374 (holding that federal law preempted a D.C. law regulating price of patented prescription drugs). Nor can plaintiffs seek to "disgorge profits from the sale of [Manufacturers'] patented drugs"—but that is exactly what Mississippi's prayer for

relief seeks, insofar as it asks for "restitution" and "disgorgement" that (it alleges) "is available under the state laws set forth in [the] Complaint." *Compare Gilead*, 102 F. Supp. 3d at 703, *with* TAC at § IX.B. Partial judgment on the pleadings to dismiss claims related to GLP-1s from this suit is therefore appropriate. *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, 751 F.3d 150, 164–65 (3d Cir. 2014) (affirming grant of Rule 12(c) motion on the basis that plaintiffs' state law claims were preempted by federal law).

None of the State's cases, Dkt. 142 at 3, are to the contrary. Plaintiffs in each of those cases alleged "misconduct in the marketplace," like fraudulent conduct before the United States Patent and Trademark Office, pay-for-delay settlements and bad-faith enforcement of expiring patents, which blocked or delayed competition from cheaper products and, as an indirect result, drove market prices up. *In re: EpiPen Mktg. Sales Pracs., and Antitrust Litig.*, 336 F. Supp. 3d 1256, 1334 (D. Kan. 2018); *see also In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 217 (S.D.N.Y. 2012) (bad-faith patent enforcement and sham patent infringement litigation); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 356-57 (D.R.I. 2017) (fraudulently procured patent); *Picone v. Shire PLC*, 2017 WL 4873506, at *14 (D. Mass. Oct. 20, 2017) (pay-for-delay settlements). In fact, the *EpiPen* plaintiffs themselves explicitly disclaimed any challenge to defendants' "rights under the patent laws to make [their own] pricing decisions." *EpiPen*, 336

F. Supp. 3d at 1333. The claims brought here by the State, by contrast, directly challenge Manufacturers' *pricing decisions*, and so are preempted as to patented products.

II. The State Fails to Allege Any Unlawful Conduct as to GLP-1s

The State's claims independently fail because it does not adequately plead any unlawful conduct as to GLP-1s. The factual allegations underlying the State's claims of unlawful conduct pertain solely to *insulin* and are absent as to GLP-1s, which (as the State necessarily acknowledges) are not insulins.

The MCPA prohibits "unfair or deceptive trade practices in or affecting commerce." Miss. Code § 75-24-5(1)–(2). Unjust enrichment and civil conspiracy likewise both require allegations of wrongdoing. Unjust enrichment requires a showing that the defendant possesses "money or property which in good conscience and justice he should not retain." *Holmes v. Lankford*, 358 So. 3d 645, 653 (Miss. Ct. App. 2023). And to "state a claim for civil conspiracy," the State must allege "one or more unlawful overt acts." *Emmerich Newspapers, Inc. v. Particle Media, Inc.*, 2022 WL 843209, at *4 (S.D. Miss. Mar. 21, 2022).

The State alleges that it satisfies all of these requirements because Manufacturers violated state law by reporting "false" or inflated prices that they set for insulin, which were "not legal, competitive or at fair market value." TAC ¶ 522 (citing Miss. Code § 75-24-5(2)(e)). Insulin prices, the State argues, do not reflect

the fair market value because "production costs of insulin have decreased" over the last ten years, *id.* ¶ 267; because insulin's "basic research . . . was performed one hundred (100) years ago" and its "more recent" improvements were completed "decades ago," *id.* ¶¶ 270–71; and because insulin has "been available in the same form since the late 1990s/early 2000s." *Id.* ¶ 265. The *Mississippi* court relied on those allegations in denying Manufacturers' motion to dismiss, concluding that "the State delineates each Manufacturer Defendant's alleged participation in the 'Insulin Pricing Scheme,'" including by alleging "knowledge, and intent." *Mississippi* Dkt. 111 at 14 (citing, among other allegations, TAC ¶¶ 265, 267, and 270–71).

Whatever may be said of those allegations as to insulin, none of them are applicable to GLP-1s. The State does not include any allegations related to GLP-1s that would support its claims. In fact, the State makes no attempt whatsoever to allege *any* causal nexus between the supposed "Insulin Pricing Scheme" and the pricing of GLP-1s. It does not claim that GLP-1s share any of the characteristics that allegedly make insulin's prices unfair, such as their age. Nor could it make such allegations. GLP-1s are new drugs—the oldest of them was approved by the FDA in 2010. TAC ¶ 277 Tbl. 1. And unlike the "Insulin Pricing Scheme"—an alleged feature of which is low research and development costs related to insulin, which the State alleges should lead to lower prices—the State alleges that "research and development costs" are often "large" for new drugs, differentiating them from the

insulins underlying the State's claims. *Id.* ¶ 270. Because it does not allege any wrongdoing with regard to GLP-1s, the State's claims as to those products should be dismissed.

At most, the State alleges that Manufacturers pay rebates to PBMs in connection with formulary access for insulins *and* GLP-1s, creating a delta between the list price of these drugs and their net price after accounting for rebates. But that is true of *every* branded pharmaceutical in America. If such an allegation were enough to state a claim, then every manufacturer that sells *any* branded drug in the United States could be sued as part of the same "Insulin Pricing Scheme." That conclusory allegation cannot be enough to state a viable cause of action, because it does not support a plausible inference of wrongdoing as to the pricing of GLP-1s. *See Iqbal*, 556 U.S. at 679 (requiring dismissal where "the well-pleaded facts" do not "plausibly give rise to an entitlement to relief").

CONCLUSION

For the reasons stated above, the Court should enter partial judgment on the pleadings in Manufacturers' favor as to GLP-1s.

Dated: June 7, 2024

/s/ Brian W. Carroll
Brian W. Carroll
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel.: (973) 639-2020

James P. Rouhandeh (*pro hac vice*)
David B. Toscano (*pro hac vice*)
DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, NY 10017
Tel.: (212) 450-4000

Neal A. Potischman (*pro hac vice*)
Andrew Yaphe (*pro hac vice*)
DAVIS POLK & WARDWELL LLP
1600 El Camino Real
Menlo Park, CA 94025
Tel.: (650) 752-2000

Attorneys for Defendant
Novo Nordisk Inc.

/s/ Liza M. Walsh (with permission)
Liza M. Walsh
Katelyn O'Reilly
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
Tel.: (973) 757-1100

Michael R. Shumaker (*pro hac vice*)
Julie E. McEvoy (*pro hac vice*)
William D. Coglianese (*pro hac vice*)
JONES DAY
51 Louisiana Ave. NW
Washington, DC 20001
Tel.: (202) 879-3939

Attorneys for Defendant
Sanofi-Aventis U.S. LLC

/s/ Melissa A. Geist (with permission)
Melissa A. Geist
REED SMITH LLP
136 Main Street, Suite 250
Princeton, NJ 08540
Tel.: (609) 514-5978

James F. Hurst (*pro hac vice*)
Andrew A. Kassof (*pro hac vice*)
Robert B. Ellis (*pro hac vice)*
Diana M. Watral (*pro hac vice*)
Ryan Moorman (*pro hac vice*)
Jason A. Feld (*pro hac vice*)
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, IL 60654
Tel.: (312) 862-2000

Attorneys for Defendant
Eli Lilly and Company

CERTIFICATE OF SERVICE

I certify that I am an Attorney at Law of the State of New Jersey and a Member of the Bar of this Court and that on this date I caused a copy of this document to be served on all counsel of record in the above-captioned matter via ECF filing.

/s/ Brian W. Carroll
Brian W. Carroll

Dated: June 7, 2024
Newark, New Jersey